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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,714	04/27/2007	Anders Carlsson	D7873.0003	5273

32172 7590 07/07/2009

DICKSTEIN SHAPIRO LLP
1177 AVENUE OF THE AMERICAS (6TH AVENUE)
NEW YORK, NY 10036-2714

EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,714	CARLSSON ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12,14,15,17-19,21-25, 27 and 28* is/are pending in the application.

4a) Of the above claim(s) *24, 25, 27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7,9-12,14,15,17-19 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1pg (08/04/06)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-7, 9-12, 14-15, 17-19 and 21-23) in the reply filed on 5/28/2009 is acknowledged. The traversal is on the ground that the constipation-dissolving property of the composition is a special technical feature which links the groups. This is not found persuasive because treating constipation was only an indented use of Groups I and II. Applicant also traverses on the ground that some claims from Group II are dependent from claims in Group I. This is not found persuasive because where unity of inventions is broken, restriction is proper among the various inventions, regardless of claim dependency.

Applicant's species elections with traverse of glycerol as the polyvalent alcohol and the lidocaine as the active agent are acknowledged. The traversal is on the ground that it is insufficient to restrict when the species are different from one another. This is not found persuasive because as explained in the restriction dated 4/22/09, the compounds vary in structure and without a common core, election of a single disclosed species is proper.

Claims 24, 25, 27, and 28 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections – 35 U.S.C. § 112—Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to whether "in a constipation-dissolving amount" refers to the oily triglyceride alone or the composition as a whole. If it refers to the composition as a whole, it is unclear as to whether it refers to the relative amounts of the components or the total amount of the composition required to be administered in order to produce the desired effect. For purposes of examination, the term is interpreted in light of the other claims (claim 28) and the specification (Page 6, Lines 15-19) as referring to the whole or total amount of the composition administered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Herslof et al. (WO 03/068267 – see PTO-892 dated 4/22/09).

Herslof teaches a rectally administered solid composition containing a galactolipid, water, and a trivalent alcohol (Claim 17, depending from claims 15, 13, 7 and 1 in series).

Note, a recitation of the intended use, for the treatment of constipation by rectal administration, of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the intended use of preventing or treating osteoporosis is met where both compositions contain the same active ingredient.

But the claims also require the composition in a "constipation-dissolving amount", as discussed in the 112 indefiniteness rejection supra. With regards to the a "constipation-dissolving amount", the claim does not limit, nor does the specification provide any boundaries with regards to what amount of composition is required to be a "constipation dissolving amount". Therefore any amount of the composition administered to a constipated patient would reasonably be expected to dissolve at least some amount of constipation.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09).

Herslof is discussed above and further teaches a rectally administered compositions (abstract) which comprise lipids from oats, including galactolipids such as digalactosyldiglycerol (DGDG), glycerol, and triglycerides (Page 6, Lines 3-29) for the treatment of conditions amenable to treatment (Claim 35).

Herslof does not teach the instantly claimed components as a preferred embodiment.

It would be obvious to one of ordinary skill in the art to pick and choose among the components discloses by Herslof to include in the rectally administrable pharmaceutical composition.

Claims 1-7, 9-12, 14, 15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09) in view of Tomaru et al. (Colonic Giant Migrating Contractions Induced by Glycerol Enema in Anesthetized Rats - Japan. J. Pharmacol. Vol. 63, Pages 525 -528, 1993)

and Klaschik et al (Constipation, Modern laxative therapy Support Care Cancer Vol. 11, Pages 679–685, 2003).

Herslof is discussed above and further teaches due to the interactions between the polar and nonpolar components, the compositions are well suited for incorporation of a pharmacologically active agent (Page 4, Lines 19-33). Herslof also teaches embodiments having varying amounts of oily triglyceride and polar lipid components where the variations affect the desired efficacy (Page 13, Table 2).

Herslof does not teach the instantly claimed component percentages of claims 9-12, 14-15 and 17, the incorporation of lidocaine, or the specific conditions which the tablets/suppository treats so as to optimize the efficacy.

Klaschik teaches that a rectally administered glycerol tablet would treat constipation (pg 683, Column 2, Rectal Laxatives). Klascheck teaches that glycerol and olive oil are known rectal laxatives and may be in the form of enemas or suppositories (Id.)

Klaschik does not teach the enemas are used to treat constipation or the addition of the specific components instantly claimed as a preferred embodiment.

Tomoru teaches that glycerol has long been used for the treatment of constipation, but often induces Giant Migrating Contractions (GMCs) (Page 525, Left Column, First Paragraph). To minimize unwanted GMCs, Tomaru teaches administration of 5% lidocaine to reduce the irritation caused by glycerol (Page 525, middle of right column).

Tomoru does not teach the addition of an oily triglyceride or a polar lipid.

It would have been obvious to one of ordinary skill in the art to administer the composition of Herslof for the treatment of constipation, given the general teachings of Klaschik that rectally administered glycerol compositions may treat the same. Further, it would be obvious to add the lidocaine to the composition of Herslof in order to reduce potential side effects, as suggested by Tomoru.

While the prior art does not specifically disclose the relative percentages with water as a preferred embodiment, the relative percentages of the various components will be adjusted by the addition of water to a range for the use disclosed by Klaschik, i.e. treating constipation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09) in view of Klaschik et al (Constipation, Modern laxative therapy Support Care Cancer Vol. 11, Pages 679–685, 2003), and Stemmle (U.S. 4,828,839).

Herslof and Klaschik et al are discussed above, but do not disclose the dynamic viscosity instantly claimed.

Stemmle teaches solid tablets and/or suppositories commonly have a dynamic viscosity in the range of about 0.3 Pa·S to about 1.4 Pa·S, where Pa·S = Ns/m^2 (See Stemmle at Column 5, Lines 1-10).

Stemmle does not teach tablets and/or suppositories with the instantly claimed components.

It would be obvious when making the suppositories made obvious by Herslof and Klaschik et al to adjust the various properties of the composition, such as the dynamic viscosity, to be within the commonly accepted range for the specific property, such as the range of dynamic viscosities taught by Stemmle.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612